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9/17/15

In re Application of :
Belouski et al. : Decision on Petition
Serial No.: 13/282,065 :
Filed: October 26, 2011 :
Docket No.: **000659-0065-103**

This letter is in response to the Petition under 37 C.F.R. 1.181, filed on August 14, 2015, for reconsideration of the Restriction Requirement.

BACKGROUND

A review of the file history shows that the application was filed with claims 1-29.

On July 24, 2014, the following restriction was made under 35 U.S.C. 121:

Group I, claims 1-11, 21-22 and 25, drawn to a method for treating a mammal in need thereof, comprising the step of administering to said mammal an anti-activin receptor-like kinase- 1 (ALK-1) antibody or an antigen-binding portion thereof, class 424, subclass 130.1+.

Group II, claims 12-20 and 23-24, drawn to a method of inhibiting angiogenesis in a mammal in need thereof, comprising the step of administering to said mammal a therapeutically effective amount of an anti-ALK- 1 antibody or an antigen-binding portion thereof, class 424, subclass 130.1+.

Group III, claims 26-29, drawn to a method for treating hepatobiliary cancer in a human in need thereof, comprising the step of administering to said human a

monoclonal antibody comprising a heavy chain amino acid sequence of SEQ ID NO: 2 and a light chain amino acid sequence of SEQ ID NO: 4, class 424, subclass 130.1+.

Applicants were also required under 35 U.S.C. 121 to elect a single disclosed species, or a single grouping of patentably indistinct species, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

On September 22, 2014, Applicants elected, with traverse, the methods of Group I. Claims 1-4, 6-8, 10, 11, 21, 22, and 30-32 encompass the elected invention. Applicants also elected, without traverse, antibodies comprising the heavy chain CDR1-3 amino acid sequences and the light chain CDR1-3 amino acid sequences of SEQ ID NOs: 6 and 8, respectively (claim 1, item a)). All of the pending claims (i.e., claims 1-4, 6-8, 10-12, 14-17, 20-34) read on the elected species. Applicants also elected, without traverse, renal cell carcinoma. Claims 1-4, 7, 8, 10-12, 14-17, 20-25, 27-30, 32 and 34 read on the elected species. Applicants also elected, without traverse, cancer and renal cell carcinoma. Claims 1-4, 7, 8, 10-12, 14-17, and 20-34 read on cancer. Claims 1-4, 7, 8, 10-12, 14-17, 20-25, 27-30, 32 and 34 read on renal cell carcinoma. Applicants also elected, without traverse, age-related macular degeneration. Claims 1, 6-8, 10-12, 14-17, and 20-24 read on the elected species. Applicants also elected, without traverse, antibodies comprising the heavy and light chain variable domain amino acid sequences of SEQ ID NOs: 6 and 8, respectively (see claim 10, item a)). Claims 1-4, 6- 8, 10-12, 14-17, and 20-34 read on the elected species. Applicants also elected, with traverse, antibodies whose heavy and light chains comprise the amino acid sequences ofSEQ ID NO: 2 and SEQ ID NO: 4, respectively (claim 11, item a)). Claims 1-4, 6-8, 10-12, 14-17, and 20-34 read on the elected species.

On December 9, 2014, the examiner mailed a non-final Office action. Claims 1-4, 6-8, 10-12, 14-17and 20-34 were pending in the application. Claims 6, 7, 12, 14-17, 20, 23-26, 31, 33 and 34 were withdrawn from consideration. Claims 1-4, 8, 10, 11, 21, 22, 27-30 and 32 were rejected. Claim 27 is objected to because of informalities. Claims 1-4, 8, 10-11, 21-22, 27-30, and 32 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, because the specification, while being enabling for treating melanoma, in vivo,

In response thereto, applicants submitted an amendment on March 9, 2015 addressing the rejections set forth in the Office action of December 9, 2014, 2014.

The examiner mailed to applicants a final Office action on April 17, 2015. In this Office action, Claims 1, 3, 7, 8, 10-12, 14-17 and 20-34 were pending in the application. Claims 1, 3, 7, 8, 10, 11, 21, 22, 27-30 and 32 were rejected. Claims 12, 14-17, 20, 23-26, 31, 33-34 remained withdrawn from consideration. The rejection of Claims 1,3, 7-8, 10-11,21-22, 27-30, and 32 under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, because the specification does not reasonably provide enablement for treating just any cancer, condition or renal cancer in any subject with the elected antibody is maintained. The examiner set forth that the Office action was final.

On August 14, 2015, applicants submitted an after final amendment.

On August 14, 2015, applicants also filed the petition discussed herein.

DISCUSSION

Applicants argue "... that there would be no serious burden on the examiner if restriction is not required. First, as noted in the Restriction Requirement itself, all of the three alleged invention groups belong to the same field of search, i.e., class 424, subclass 130.1. *See also* Statement of Facts, para. 4. Second, there is no serious burden on the examiner to search and examine all three invention groups together. All three groups are directed to methods of treatment. The claims in each invention group recite four elements: (1) the subject to be treated; (2) the treatment effect; (3) the treatment step(s); and (4) the molecule used in the treatment. Search and examination of claims of Group I necessarily encompasses search and examination of Groups II and III."

Applicants' argument has been carefully considered and it is persuasive for applicants' reason above that there is no serious burden on the examiner to search and examine all three invention groups together.

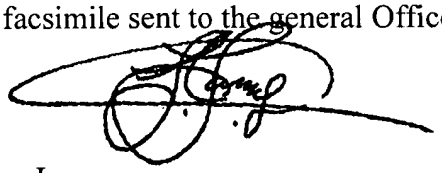
DECISION

The petition is **GRANTED**.

The final restriction requirement of April 17, 2015 is hereby vacated.

The application will be forwarded to the examiner for the preparation of a non-final Office action consistent with this decision herein, namely that the examiner will search and examine all three invention groups together.

Should there be any questions about this decision please contact Marianne C. Seidel, by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0584 or by facsimile sent to the general Office facsimile number, 571-273-8300.



Jerry Lorengo
Director, Technology Center 1600

000659-0065-103

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Shelley Sims Belouski *et al.*
Application No.	:	13/282,065
Filed	:	October 26, 2011
Conf. No.	:	8594
For	:	HUMAN MONOCLONAL ANTIBODIES TO ACTIVIN RECEPTOR-LIKE KINASE-1
Group Art Unit	:	1643
Examiner	:	Lynn Anne Bristol

New York, New York
August 14, 2015

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

PETITION FROM REQUIREMENT FOR RESTRICTION

Sir:

Applicants hereby petition the Director to review the July 24, 2014 Restriction Requirement. 37 C.F.R. §§ 1.144 and 1.181.

Applicants have not filed any appeal in this application. Further, applicants requested reconsideration of this Restriction Requirement in accordance with 37 C.F.R. § 1.143 in their September 22, 2014 response to the Restriction Requirement. Thus, the condition for this petition to be considered under 37 C.F.R. § 1.144 is met.

I. THE DIRECTOR'S ACTION BEING REQUESTED

Applicants petition the Director to review the July 24, 2014 Restriction Requirement and the prosecution history related thereto, and to withdraw the restriction among the three invention groups set forth in the Requirement. For the Director's convenience, a current Listing of Claims is provided in Appendix 1.

II. STATEMENT OF FACTS

The July 24, 2014 Restriction Requirement

1. In the July 24, 2014 Restriction Requirement, the Examiner required election of one of the following three alleged invention groups for examination:

> Group I (Claims 1-11, 21, 22, and 25), drawn to a method for treating a mammal in need thereof, comprising the step of administering to said mammal an anti-activin receptor-like kinase- 1 (ALK-1) antibody or an antigen-binding portion thereof;
>
> Group II (Claims 12-20, 23, and 24), drawn to a method for inhibiting angiogenesis in a mammal in need thereof, comprising the step of administering to said mammal a therapeutically effective amount of an anti-ALK- 1 antibody or an antigen-binding portion thereof; and
>
> Group III (Claims 26-29), drawn to a method for treating hepatobiliary cancer in a human in need thereof, comprising the step of administering to said human a monoclonal antibody comprising a heavy chain amino acid sequence of SEQ ID NO: 2 and a light chain amino acid sequence of SEQ ID NO: 4.

See pp. 2-4 of the Requirement.

2. The Examiner also required election of various species. Those species requirements are not the subject of this petition.

Applicants' September 22, 2014 Response

3. In their September 22, 2014 Response, applicants elected Group I with traverse (*see* p. 14 of the Response).

4. Applicants pointed out that the Restriction Requirement categorized all three invention groups into the same field of search, i.e., class 424, subclass 130.1 (*see* p. 15 of the Response).

5. Applicants argued that search and examination of the Group I claims would encompass the search and examination of the Group II and III claims (*see* pp. 15 and 16 of the Response).

6. Applicants concluded that the Restriction Requirement is improper with regard to the three invention groups because there is no serious burden on the Examiner to search and examine all three invention groups together (*see* p. 17 of the Response).

The Examiner's December 9, 2014 Reply

7. In the December 9, 2014 Nonfinal Office Action, the Examiner made the Restriction Requirement final over applicants' traversal (*see* p. 2 of the Office Action).

8. The Examiner stated that the "traversal is on the ground(s) that the [three groups] are co-extensive[1] and would not require a burden for searching" (*see* p. 2 of the Office Action).

9. The Examiner argued that the scope of elected Group I (treatment of "a human in need thereof") "far exceeds a cancer . . . . Accordingly, where is the Examiner to begin searching for art as well as determining patentability under [Section 112], when the need(s) of the human are undefined in the claim?" (*see* p. 2 of the Office Action).

[1] The Examiner mischaracterized applicants' traversal: while applicants did argue that there is no extra burden to search additionally Group II and Group III, they did not say that the three groups are "co-extensive."

10. The Examiner further stated that the target endpoint for Group II (inhibiting angiogenesis in a human in need thereof) and the target endpoint for Group III (treating hepatobiliary cancer or renal cell carcinoma[2] in a human in need thereof) are not necessarily the same.

III. REASONS FOR THE REQUESTED ACTION

The restriction among the three invention groups set forth in the Restriction Requirement is improper and should be withdrawn. The MPEP sets forth two criteria for a proper requirement for restriction between patentably distinct inventions: (A) the inventions must be independent or distinct as claimed; and (B) there would be a serious burden on the examiner if restriction is not required. See, e.g., M.P.E.P. § 803. The MPEP further provides:

> If the search and examinations of all the claims in an application can be made without serious burden, the examiner **must** examine them on the merits, even though they include claims to independent or distinct inventions. *Id.* (emphasis added)

Applicants submit that there would be no serious burden on the examiner if restriction is not required.

First, as noted in the Restriction Requirement itself, all of the three alleged invention groups belong to the same field of search, i.e., class 424, subclass 130.1. *See also* Statement of Facts, para. 4.

Second, there is no serious burden on the examiner to search and examine all three invention groups together. All three groups are directed to methods of treatment.

[2] Claim 27 in Group III was amended in applicants' September 22, 2014 Response to recite "treating renal cell carcinoma in a human."

The claims in each invention group recite four elements: (1) the subject to be treated; (2) the treatment effect; (3) the treatment step(s); and (4) the molecule used in the treatment. Search and examination of claims of Group I necessarily encompasses search and examination of Groups II and III.

With regard to the subject to be treated, both Groups I and II recite "a human in need thereof" (independent claims 1, 12, and 17), and Group III recites "a human" with hepatobiliary cancer or renal cell carcinoma (independent claims 26 and 27). These two cancer types are listed in claim 3, which has been designated by the Examiner as belonging to Group I. Further, in response to the Examiner's species election requirement, applicants elected the species "cancer" from a genus of conditions to be treated and the species "renal cell carcinoma" from a genus of "abnormal cell growth." *See* September 22, 2014 Response, p. 18. As a result, search and examination of the generic "a human in need thereof" in the context of the elected species would encompass search and examination of "a human" with "cancer" and with "renal cell carcinoma."

With regard to the effect of treatment, the Group I and III independent claims generically recite "treating" (claims 1, 26, and 27), while the Group II independent claims recite specifically "inhibiting angiogenesis" (claims 12 and 17). The term "inhibiting angiogenesis" is recited in former claim 5 (now claim 7), which has been designated by the Examiner as belonging to Group I. Search and examination of that claim would encompass search and examination of Group II in the "angiogenesis" aspect.

With regard to the treatment step(s), all the pending claims recite, directly or through claim dependency, a single step—administering an antibody to a subject. Thus, search and examination of this single step would be common to all three invention groups.

With regard to the molecule used in the treatment, the Group I claims recite an antibody comprising, *inter alia*, the heavy chain CDR1-3 amino acid sequences in SEQ ID NO: 6 and the light chain CDR1-3 amino acid sequences in SEQ ID NO: 8 (independent claim 1). SEQ ID NOs: 6 and 8 comprise the heavy and light chain variable domain amino acid sequences of 1.12.1(M29I/D19A). Thus, the Group I claims recite an antibody having the six CDRs of 1.12.1(M29I/D19A). Group II has two independent claims, claims 12 and 17. Like claim 1, claim 12 recites an antibody having the 6 CDRs of 1.12.1(M29I/D19A). Claim 17 recites an antibody whose V_H and V_L amino acid sequences are encoded by the nucleotide sequences of the plasmid inserts in the *E. coli* clones having ATCC accession numbers PTA-6864 and PTA-6865, respectively. These V_H and V_L sequences also are those of 1.12.1(M29I/D19A). See, e.g., the specification at paragraph [0429]. Group III has two independent claims, claims 26 and 27. Both claims recite an antibody whose heavy and light chains comprise the amino acid sequences of SEQ ID NOs: 2 and 4, respectively. These two amino acid sequences are those of the heavy and light chains of 1.12.1(M29I/D19A). See, Table 1 of the specification. Accordingly, each Group defined by the Examiner recites administration of an antibody comprising the six CDRs of antibody 1.12.1(M29I/D19A).

Because the Groups defined by the Examiner are in the same search field, and as discussed above, search and examination of the Group I claims would encompass the search and examination of the Group II and III claims, there can be no serious burden on the Examiner if restriction is not required. *See also* Statement of Facts, paras. 5 and 6.

The Examiner's December 9, 2014 reply to applicants' traversal failed to establish that a search burden exists without the restriction requirement. The Examiner advanced two grounds for maintaining the restriction requirement among the three invention groups. But neither ground withstands careful analysis.

First, the Examiner alleged that due to the breadth of claim 1 (which encompasses treatment of cancerous as well as noncancerous conditions), there was no place for her to start search and examination for the purposes of Section 112. *See* Statement of Facts, para. 9. The Examiner's alleged difficulty can be addressed by a species election requirement. The Examiner indeed required applicants to elect a condition to be treated, and applicants had complied, by electing "cancer" and "renal cell carcinoma." This species election could be applied to Group II and Group III as well.

The Examiner also alleged that a search burden would exist without the restriction requirement because the target endpoint for Group II claims (inhibiting angiogenesis) and the target endpoint for Group III claims (treating hepatobiliary cancer or renal cell carcinoma) may not be the same. *See* Statement of Facts, para. 10. That argument is flawed as well. First, the target endpoint of "inhibiting angiogenesis" is recited in a Group I claim (claim 5). Through claim dependency, that target endpoint is linked to the list of cancers (including hepatobiliary cancer and renal cell carcinoma)

recited in claim 3, another Group I claim. Second, as discussed in applicants' responses to the December 9, 2014 Nonfinal Office Action and the April 17, 2015 Final Office Action, the role of angiogenesis in cancer development was well known in the art at the priority date of this application. The specification also discloses experimental data showing the anti-ALK-1 antibodies recited in the restricted claims inhibit angiogenesis *in vitro* and *in vivo*. Thus, search and examination of claims 3 and 5 in Group I can be extended to search and examination of Group II and III without significant burden.

IV. CONCLUSION

For at least the foregoing reasons, applicants submit that no significant burden will result from search and examination of Groups I, II, and III together. Applicants respectfully petition the Director to withdraw the restriction requirement imposed on these three invention groups.

Applicants believe that no fee is due with this petition. However, if a fee is due, please charge it to our Deposit Account No. 06-1075, under Order No. 000659-0065-103.

Respectfully submitted,

/Z. YING LI/

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APPENDIX 1

LISTING OF CLAIMS

1. (Previously Presented) A method for treating cancer in a human in need thereof, comprising the step of administering to said human an anti-activin receptor-like kinase-1 (ALK-1) antibody or an antigen-binding portion thereof, wherein said antibody comprises the heavy chain CDR1-3 and the light chain CDR1-3 found in the following amino acid sequences, respectively:

a) SEQ ID NO: 6 and SEQ ID NO: 8;

b) SEQ ID NO: 14 and SEQ ID NO: 16;

c) SEQ ID NO: 18 and SEQ ID NO: 20;

d) SEQ ID NO: 26 and SEQ ID NO: 28;

e) SEQ ID NO: 30 and SEQ ID NO: 32;

f) SEQ ID NO: 38 and SEQ ID NO: 40;

g) SEQ ID NO: 46 and SEQ ID NO: 48;

h) SEQ ID NO: 50 and SEQ ID NO: 52;

i) SEQ ID NO: 54 and SEQ ID NO: 56;

j) SEQ ID NO: 58 and SEQ ID NO: 60;

k) SEQ ID NO: 62 and SEQ ID NO: 64;

l) SEQ ID NO: 66 and SEQ ID NO: 68; or

m) SEQ ID NO: 70 and SEQ ID NO: 72.

2. (Canceled)

3. (Previously Presented) The method according to claim 1, wherein said cancer is selected from melanoma; mesothelioma; renal cell carcinoma; breast cancer; head and neck cancer; brain cancer; cervical cancer; prostate cancer; pancreatic cancer; testicular cancer; hepatobiliary cancer; hepatic duct cancer; biliary duct cancer; bladder cancer; urethral cancer; lung cancer; non-small cell lung cancer; small cell lung cancer; ovarian cancer; colon cancer; rectal cancer; and cancer of the anal region.

4-6. (Canceled)

7. (Previously Presented) The method according to claim 1 or 3, wherein said method inhibits angiogenesis.

8. (Original) The method according to claim 1, wherein said antibody is a human antibody.

9. (Canceled)

10. (Previously Presented) The method according to claim 1, wherein the heavy chain and the light chain of said antibody comprise the following amino acid sequences, respectively:

a) SEQ ID NO: 6 and SEQ ID NO: 8;

b) SEQ ID NO: 14 and SEQ ID NO: 16;

c) SEQ ID NO: 18 and SEQ ID NO: 20;

d) SEQ ID NO: 26 and SEQ ID NO: 28;

e) SEQ ID NO: 30 and SEQ ID NO: 32;

f) SEQ ID NO: 38 and SEQ ID NO: 40;

g) SEQ ID NO: 46 and SEQ ID NO: 48;

h) SEQ ID NO: 50 and SEQ ID NO: 52;

i) SEQ ID NO: 54 and SEQ ID NO: 56;

j) SEQ ID NO: 58 and SEQ ID NO: 60;

k) SEQ ID NO: 62 and SEQ ID NO: 64;

l) SEQ ID NO: 66 and SEQ ID NO: 68;

m) SEQ ID NO: 70 and SEQ ID NO: 72;

n) SEQ ID NO: 104 and SEQ ID NO: 127;

o) SEQ ID NO: 6 and SEQ ID NO: 127; or

p) SEQ ID NO: 104 and SEQ ID NO: 8.

11. (Original) The method according to claim 1, wherein the heavy chain and the light chain of said antibody comprise the following amino acid sequences, respectively:

a) SEQ ID NO: 2 and SEQ ID NO: 4;

b) SEQ ID NO: 2 and SEQ ID NO: 102;

c) SEQ ID NO: 100 and SEQ ID NO: 4; or

d) SEQ ID NO: 100 and SEQ ID NO: 102.

12. (Withdrawn) A method of inhibiting angiogenesis in a human suffering from cancer, the method comprising the step of administering to said human a therapeutically effective amount of an anti-ALK-1 antibody or an antigen-binding portion thereof, wherein said antibody comprises the heavy chain CDR1, CDR2, and CDR3 amino acid sequences in SEQ ID NO: 6 and the light chain CDR1, CDR2, and CDR3 amino acid sequences in SEQ ID NO: 8.

13. (Canceled)

14. (Withdrawn) The method according to claim 12, wherein said antibody is a human antibody.

15. (Withdrawn) The method according to claim 12, wherein said antibody comprises a heavy chain comprising the amino acid sequence of SEQ ID NO: 6 and a light chain comprising the amino acid sequence of SEQ ID NO: 8.

16. (Withdrawn) The method according to claim 12, wherein said antibody comprises a heavy chain comprising the amino acid sequence of

SEQ ID NO: 2 and a light chain comprising the amino acid sequence of SEQ ID NO: 4.

17. (Withdrawn) A method of inhibiting angiogenesis in a human suffering from cancer, the method comprising the step of administering to said human a therapeutically effective amount of an antibody or an antigen-binding portion thereof, wherein said antibody comprises a V_H amino acid sequence encoded by the nucleotide sequence of the plasmid insert found in the *E. coli* clone deposited under ATCC accession number PTA-6864, and wherein said antibody further comprises a V_L amino acid sequence encoded by the nucleotide sequence of the plasmid insert found in the *E. coli* clone deposited under ATCC accession number PTA-6865.

18-19. (Canceled)

20. (Withdrawn) The method according to claim 17, wherein said antibody is a human antibody.

21. (Previously Presented) The method according to claim 1, wherein said antibody or antigen-binding portion is derivatized or linked to another molecule.

22. (Previously Presented) The method according to claim 21, wherein said molecule is a detection agent, a cytotoxic agent, a pharmaceutical agent, a peptide or a protein.

23. (Withdrawn) The method according to claim 17, wherein said antibody or antigen-binding portion is derivatized or linked to another molecule.

24. (Withdrawn) The method according to claim 23, wherein said molecule is a detection agent, a cytotoxic agent, a pharmaceutical agent, a peptide or a protein.

25. (Withdrawn) The method according to claim 17, wherein the human suffers from a cancer selected from melanoma; mesothelioma; renal cell carcinoma; breast cancer; head and neck cancer; brain cancer; cervical cancer; prostate cancer; pancreatic cancer; testicular cancer; hepatobiliary cancer; hepatic duct cancer; biliary duct cancer; bladder cancer; urethral cancer; lung cancer; non-small cell lung cancer; small cell lung cancer; ovarian cancer; colon cancer; rectal cancer; and cancer of the anal region.

26. (Withdrawn) A method for treating hepatobiliary cancer in a human in need thereof, comprising the step of administering to said human a

monoclonal antibody comprising a heavy chain amino acid sequence of SEQ ID NO: 2 and a light chain amino acid sequence of SEQ ID NO: 4.

27. (Previously Presented) A method for treating renal cell carcinoma in a human in need thereof, comprising the step of administering to said human a monoclonal antibody comprising a heavy chain amino acid sequence of SEQ ID NO: 2 and a light chain amino acid sequence of SEQ ID NO: 4.

28. (Previously Presented) The method according to claim 26 or 27, wherein said antibody is derivatized or linked to another molecule.

29. (Previously Presented) The method according to claim 28, wherein said molecule is a detection agent, a cytotoxic agent, a pharmaceutical agent, a peptide or a protein.

30. (Previously Presented) The method according to claim 1, wherein the cancer is a solid tumor.

31. (Withdrawn) The method according to claim 3, wherein the cancer is hepatobiliary cancer.

32. (Previously Presented) The method according to claim 3, wherein the cancer is renal cell carcinoma.

33. (Withdrawn) The method according to claim 12 or 17, wherein human suffers from hepatobiliary cancer.

34. (Withdrawn) The method according to claim 12 or 17, wherein the human suffers from renal cell carcinoma.